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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,271	07/23/2003	Terry R. Hobbs	58017US002	8409

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EXAMINER

PAK, JOHN D

ART UNIT	PAPER NUMBER
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1616

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/28/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/625,271

Applicant(s)

HOBBS ET AL.

Examiner

JOHN PAK

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5-14, 16, 24-27, 37 and 38 is/are pending in the application.
- 4a) Of the above claim(s) 28-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-14, 16, 24-27, 37 and 38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Claims 1-3, 5-14, 16, 24-38 are pending in this application. Claims 28-36 remain withdrawn from further consideration as being directed to non-elected subject matter.

Claims **1-3, 5-14, 16, 24-27 and 37-38** will presently be examined.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5-8, 10, 13-14, 16, 24, 26-27, 37-38 stand/are rejected under 35 U.S.C. 102(b) as being anticipated by Devillez (US 5,736,582) for the reasons of record (see the Office action of 6/6/2005, pages 4-6).

Devillez explicitly discloses a skin treating composition that contains, inter alia, the following ingredients at pH 4.6:

3.5 wt% hydrogen peroxide (calculated from 10% of a 35% solution);

1 wt% salicylic acid;

1.67 wt% cetyl alcohol;

74.8 wt% distilled water;

0.3 wt% sodium hydroxide;

0.06 wt% simethicone (has antifoam properties);

0.31 wt% sodium lauryl sulfate;

1.86 wt% Promulgen G (stearyl alcohol + cetareth-20).

See column 6, lines 45-56 and column 7, lines 28-30.

The claims are thereby anticipated. The kill rate feature in claim 2 is noted, but such feature is deemed to be an inherent characteristic of Devillez's composition that contains the same exact ingredients as applicant's composition. Additionally, such kill rate can depend on the challenge level and the particular bacteria strain. As a result, when the Examiner can show a prior art composition that contains the same ingredients as the claimed invention, the burden of showing that the prior art composition does not somehow have the same properties shifts to applicant. MPEP 2112, 2112.01. Claim 3 requires both an aromatic acid and a salt of the aromatic acid. It is noted that Devillez's composition has sodium hydroxide added to it, q.s. pH 4.6. Sodium hydroxide would then necessarily produce the salt form of the acid and render some salt form to be present in the composition. See for example applicant's agreement on this point (in situ salt) in the instant specification, page 9, lines 1-3. Claim 24 is newly included in this ground of rejection because of applicant's amendment thereto – claim 24 reads on the solvent being optional. Claim 26 requires the composition to be more resistant to catalase deactivation than an aqueous solution of hydrogen peroxide. The Examiner's position is that since Devillez's composition contains the same ingredients as applicant's composition, the same resistance must necessarily be present. Method of claim 37 is noted but such method would necessarily have been obtained from Devillez's teachings since the ingredients must be combined in order to obtain the

mixture of ingredients. All other claim features are plainly encompassed by Devillez's composition, as shown above.

Applicant's arguments of 4/17/2006 relative to this ground of rejection has been given due consideration but they were deemed unpersuasive. The Examiner cannot understand applicant's criticism of Devillez when the disclosure directly reads on applicant's claim language. Devillez discloses the same exact pH as applicant, the same exact hydrogen peroxide concentration as applicant, the same exact aromatic acid concentration as applicant, and the same exact surfactant concentration as applicant. If applicant still believes Devillez does not somehow wind up with sufficient benzoic acid due to the NaOH (which by the way reads on applicant's claim 3, as discussed above), it is for applicant to show otherwise through objective evidence. The Examiner does not have access to laboratory facilities to test every prior art disclosure that a patent applicant may criticize. When the Examiner has met his burden, as here, the burden shifts to applicant to show through objective evidence that the prior art composition, which contains the same exact ingredients as applicant's invention, does not in fact possess the properties claimed by applicant.

Applicant further argues that Devillez uses more ingredients than are within the scope of the present claim 1, as amended. The Examiner cannot agree. Applicant is in error in believing that the amendatory language, "consisting essentially of" operates to exclude some of Devillez's ingredients. The "consisting essentially of" language

excludes ingredients that would materially alter the basic and novel characteristics of applicant's invention. MPEP 2111.03. If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. In re De Lajarte, 143 USPQ 256 (CCPA 1964). The Examiner finds Devillez's ingredients are not excluded because applicant's invention includes myriad and diverse composition ingredients. See the reproduced portions of the specification pages 10 & 11:

Other surfactants may also be used in this invention either alone or in combination with anionic surfactants. Such other surfactants may include amine oxides, phenol ethoxylates, fatty acid amides, sorbitan esters, fatty alcohol ethoxylates and block copolymers of ethylene oxide and propylene oxide such as that known under the trade designation "Pluronics" manufactured by BASF. In general, anionic surfactants may be used in formulations that are designed for the high level disinfection of certain endoscopes, for example.

Optional additional components may be included in the compositions of the invention such as: antifoaming agents, foaming agents, corrosion inhibitors, peroxide stabilizing agents, hydrotropes, fragrances, and colorants. Suitable corrosion inhibitors include nitrates, azoles such as benzotriazole, and imidazoles. Tin compounds and pyrophosphates are examples of suitable peroxide stabilizers. These optional components may be included in the compositions of the invention at a concentration level in the ready to use compositions of up to about 10% by weight. Exact amounts of the individual optional components is within the ordinary skill of those working in the art. Other components known to those skilled in the art may also be included in the composition to alter or tailor the basic composition to a particular need.

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With such divergent surfactant types and additional components, applicant's argument that Devillez's additional composition ingredients are excluded by the "consisting essentially of" language is most unpersuasive.

Claims 1-2, 5-14, 24, 26, 37-38 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 966883.

EP 966883 explicitly discloses a formulation E, wherein the following components are contained (page 10):

- 2 wt% benzoic acid;
- 2 wt% amine oxide;
- 2 wt% alkyl sulfate;
- 0.02 wt% thymol;
- 1 wt% hydrogen peroxide; and
- water to balance.

The claims are thereby anticipated. The kill rate feature in claim 2 is noted, but such feature is deemed to be an inherent characteristic of the cited prior art composition that contains the same exact ingredients as applicant's composition. Additionally, such kill rate can depend on the challenge level and the particular bacteria strain. As a result, when the Examiner can show a prior art composition that contains the same ingredients as the claimed invention, the burden of showing that the prior art

composition does not somehow have the same properties shifts to applicant. MPEP 2112, 2112.01. Claims 11 and 24 are included in this ground of rejection because those ingredients are not actually required according to applicant's claim language structure. Less than 5 wt% reads on 0% or 0% of that particular substance, and optional solvent reads on 0% solvent. Claim 26 requires the composition to be more resistant to catalase deactivation than an aqueous solution of hydrogen peroxide. The Examiner's position is that since the prior art composition contains the same ingredients as applicant's composition, the same resistance must necessarily be present. Method of claim 37 is noted but such method would necessarily have been obtained from the cited prior art teachings since the ingredients must be combined in order to obtain the mixture of ingredients. Feature of claim 38 (formulated for application to skin) is noted, but the components of the cited prior art composition E would be capable of being applied to the skin. All other claim features are plainly encompassed by the prior art composition, as shown above.

Applicant's "consisting essentially of" language has been discussed in full above, and the discussion there is incorporated herein by reference. The ingredients of the cited prior art composition E would not be excluded by the claim language for the reasons stated above.

Claims 1-3, 5-14, 16, 24-27 and 37-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Devillez (US 5,958,984).

Devillez explicitly discloses a skin treating composition that contains the following ingredients at pH 4.6:

3.5 wt% hydrogen peroxide (calculated from 10% of a 35% solution);

1 wt% salicylic acid;

10 wt% propylene glycol;

1.6 wt% cetyl alcohol;

74 wt% distilled water;

0.3 wt% sodium hydroxide;

1.8 wt% Promulgen G (stearyl alcohol + ceteareth-20);

0.06 wt% simethicone; and

0.3 wt% sodium lauryl sulfate.

See the paragraph bridging columns 6-7 and the "ACNE SKIN TREATMENT COMPOSITION." The claims are thereby anticipated. The kill rate feature in claim 2 is noted, but such feature is deemed to be an inherent characteristic of Devillez's composition that contains the same exact ingredients as applicant's composition. Additionally, such kill rate can depend on the challenge level and the particular bacteria strain. As a result, when the Examiner can show a prior art composition that contains the same ingredients as the claimed invention, the burden of showing that the prior art

composition does not somehow have the same properties shifts to applicant. MPEP 2112, 2112.01. Claim 3 requires both an aromatic acid and a salt of the aromatic acid. It is noted that Devillez's composition has sodium hydroxide added to it, q.s. pH 4.6. Sodium hydroxide would then necessarily produce the salt form of the acid and render some salt form to be present in the composition. See for example applicant's agreement on this point (in situ salt) in the instant specification, page 9, lines 1-3. Components of claims 11-12 are included here because applicant's claim structure/language leaves open such components as optional. Claim 26 requires the composition to be more resistant to catalase deactivation than an aqueous solution of hydrogen peroxide. The Examiner's position is that since Devillez's composition contains the same ingredients as applicant's composition, the same resistance must necessarily be present. Method of claim 37 is noted but such method would necessarily have been obtained from Devillez's teachings since the ingredients must be combined in order to obtain the mixture of ingredients. Applicant's "consisting essentially of" language has been discussed in full above, and the discussion there is incorporated herein by reference. The ingredients of the cited prior art composition E would not be excluded by the claim language for the reasons stated above. All other claim features are plainly encompassed by Devillez's composition, as shown above.

All claims are thereby rejected. No claim is allowed. Ground of rejection from the previous Office action that is not repeated herein is hereby withdrawn in view of applicant's claim amendments.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to JOHN PAK whose telephone number is **(571)272-0620**. The Examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE, Johann Richter, can be reached on **(571)272-0646**.

The fax phone number for the organization where this application or proceeding is assigned is **(571)273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



John Pak
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